Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Treatment of medication overuse headache – guideline of the EFNS headache panel.

Bibliographic Source(s)

Evers S, Jensen R, European Federation of Neurological Societies. Treatment of medication overuse headache--guideline of the EFNS headache panel. Eur J Neurol. 2011 Sep;18(9):1115-21. [57 references] PubMed

Guideline Status

This is the current release of the guideline.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

Recommendations

Major Recommendations

The levels of evidence (Class I-IV) supporting the recommendations and ratings of recommendations (A-C, Good Practice Point [GPP]) are defined at the end of the "Major Recommendations" field.

Recommendations for the Treatment of Medication Overuse Headache (MOH)

1. Patients with MOH should be offered advice and teaching to encourage withdrawal treatment (Level B).
2. There is no general evidence whether abrupt or tapering withdrawal treatment should be preferred. For the overuse of analgesics,

ergotamine derivatives, or triptans, abrupt withdrawal is recommended. For the overuse of opioids, benzodiazepines, or barbiturates, tapering down of the medication should be offered. (Good Practice Point)
3. The type of withdrawal treatment (inpatient, outpatient, advice alone) does not influence the success of the treatment and the relapse rate in general. (Level A)
4. In patients with opioid, benzodiazepine, or barbiturate overuse, with severe psychiatric or medical comorbidity or with failure of a previous outpatient withdrawal treatment, inpatient withdrawal treatment should be offered. (Good Practice Point)
5. Individualized preventive medication should be started at the first day of withdrawal treatment or even before if applicable. (Level C)
6. Topiramate 100 mg (up to 200 mg maximum) per day is probably effective in the treatment of MOH. (Level B)
7. Corticosteroids (at least 60 mg prednisone or prednisolone) and amitriptyline (up to 50 mg) are possibly effective in the treatment of withdrawal symptoms. (Good Practice Point)
8. Patients after withdrawal therapy should be followed up regularly to prevent relapse of medication overuse. (Good Practice Point)

Definitions:

Evidence Classification Scheme for a Therapeutic Intervention

Class I: An adequately powered prospective, randomized, controlled clinical trial with masked outcome assessment in a representative population or an adequately powered systematic review of prospective randomized controlled clinical trials with masked outcome assessment in representative populations. The following are required:

a. Randomization concealment
b. Primary outcome(s) is/are clearly defined
c. Exclusion/inclusion criteria are clearly defined
d. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias
e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences

Class II: Prospective matched-group cohort study in a representative population with masked outcome assessment that meets a–e above or a randomized, controlled trial in a representative population that lacks one criteria a–e.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment.

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

Level of Recommendations

Level A: Established as effective, ineffective, or harmful by at least one convincing class I study or at least two consistent, convincing class II studies

Level B: Probably effective, ineffective, or harmful by at least one convincing class II study or overwhelming class III evidence

Level C: Possibly effective, ineffective, or harmful by at least two convincing class III studies

Good practice point: Lack of evidence but consensus within the task force

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Medication overuse headache (MOH), including

- Ergotamine-overuse headache

- Triptan-overuse headache
- Analgesic-overuse headache
- Opioid-overuse headache
- Combination analgesic-overuse headache
- MOH attributed to the combination of acute medications
- Headache attributed to other medication misuse

Guideline Category

Counseling

Management

Prevention

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Neurology

Pediatrics

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To give recommendations for the treatment of medication overuse headache (MOH) as classified by the International Headache Society (IHS)
- To give recommendations for the specific management of MOH including the treatment of withdrawal headache

Target Population

Patients with medication overuse headaches (MOH)

Interventions and Practices Considered

Treatment/Management

1. Advice and teaching to encourage withdrawal treatment
2. Withdrawal treatment
    - Abrupt withdrawal for overuse of analgesics, ergotamine, derivatives, or triptans

    - Tapering withdrawal for the overuse of opioids, benzodiazepines, or barbiturates
3. Inpatient or outpatient withdrawal treatment
4. Individualized preventive medication started on the first day of withdrawal treatment
5. Corticosteroids and amitriptyline for withdrawal symptoms
6. Follow-up to prevent relapse

Major Outcomes Considered

- Duration of medication overuse headache (MOH)
- Headache frequency after withdrawal
- Relapse rate
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A literature search was performed using the reference databases MedLine, Science Citation Index, and the Cochrane Library; the key words used were "headache" together with the term "medication overuse" or "drug-induced" (last search in January 2011). All articles published in English, German, or French were considered when they described a controlled trial or a case report or series on the treatment of one of these headache disorders. In addition, a review book was considered.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Classification Scheme for a Therapeutic Intervention

Class I: An adequately powered prospective, randomized, controlled clinical trial with masked outcome assessment in a representative population or an adequately powered systematic review of prospective randomized controlled clinical trials with masked outcome assessment in representative populations. The following are required:

a. Randomization concealment
b. Primary outcome(s) is/are clearly defined
c. Exclusion/inclusion criteria are clearly defined
d. Adequate accounting for dropouts and crossovers with numbers sufficiently low to have minimal potential for bias
e. Relevant baseline characteristics are presented and substantially equivalent among treatment groups or there is appropriate statistical adjustment for differences

Class II: Prospective matched-group cohort study in a representative population with masked outcome assessment that meets a–e above or a randomized, controlled trial in a representative population that lacks one criteria a–e.

Class III: All other controlled trials (including well-defined natural history controls or patients serving as own controls) in a representative population, where outcome assessment is independent of patient treatment.

Class IV: Evidence from uncontrolled studies, case series, case reports, or expert opinion.

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

The recommendations are based on the scientific evidence from clinical trials and on the expert consensus by the respective task force of the European Federation of Neurological Societies (EFNS). The definitions of the recommendation levels follow the EFNS criteria (see the "Rating Scheme for the Strength of Recommendations" field).

Rating Scheme for the Strength of the Recommendations

Level of Recommendations

Level A: Established as effective, ineffective, or harmful by at least one convincing class I study or at least two consistent, convincing class II studies

Level B: Probably effective, ineffective, or harmful by at least one convincing class II study or overwhelming class III evidence

Level C: Possibly effective, ineffective, or harmful by at least two convincing class III studies

Good practice point: Lack of evidence but consensus within the task force

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

The guidelines were validated according to the European Federation of Neurological Societies (EFNS) criteria (see the "Availability of Companion Documents" field).

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate treatment of medication overuse headache (MOH)

Potential Harms

- Main medication withdrawal symptoms are worsening of the headache, nausea, vomiting, arterial hypotension, tachycardia, sleep disturbances, restlessness, anxiety, and nervousness. These symptoms normally last between 2 and 10 days but can persist for up to 4 weeks. The withdrawal headache was shorter in patients having taken triptans (mean 4.1 days) than ergotamine derivatives (mean 6.7 days) or nonsteroidal anti-inflammatory drugs (NSAIDs) (mean 9.5 days).
- In a double-blind trial in patients with a specific diagnosis of chronic migraine with medication overuse, side effects were reported by 75 percent of the patients in the topiramate group compared with 37 percent in the placebo group.

Qualifying Statements

Qualifying Statements

This guideline provides the view of an expert task force appointed by the Scientific Committee of the European Federation of Neurological Societies (EFNS). It represents a peer-reviewed statement of minimum desirable standards for the guidance of practice based on the best available evidence. It is not intended to have legally binding implications in individual cases.

Implementation of the Guideline

Description of Implementation Strategy

The European Federation of Neurological Societies (EFNS) has a mailing list and all guideline papers go to national societies, national ministries of health, World Health Organisation, European Union, and a number of other destinations. Corporate support is recruited to buy large numbers of reprints of the guideline papers and permission is given to sponsoring companies to distribute the guideline papers from their commercial channels, provided there is no advertising attached.

Implementation Tools

Staff Training/Competency Material

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report

Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Sep

Guideline Developer(s)

European Academy of Neurology - Medical Specialty Society

Source(s) of Funding

European Federation of Neurological Societies

Guideline Committee

European Federation of Neurological Societies Task Force on Medication Overuse Headache

Composition of Group That Authored the Guideline

Task Force Members: S. Evers, Department of Neurology, University of Munster, Munster, Germany; R. Jensen, Danish Headache Center, Department of Neurology, Glostrup Hospital, University of Copenhagen, Copenhagen, Denmark

Financial Disclosures/Conflicts of Interest

None

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the European Journal of Neurology Web site .

Availability of Companion Documents

The following are available:

- Brainin M, Barnes M, Baron JC, Gilhus NE, Hughes R, Selmaj K, Waldemar G; Guideline Standards Subcommittee of the EFNS Scientific Committee. Guidance for the preparation of neurological management guidelines by EFNS scientific task forces – revised recommendations 2004. Eur J Neurol. 2004 Sep;11(9):577-81. Electronic copies: Available in Portable Document Format (PDF) from the European Federation of Neurological Societies Web site .
- Continuing Medical Education is available from the European Federation of Neurological Societies Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on June 12, 2012. The information was verified by the guideline developer on July 11, 2012. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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